

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

RIBAPHARM, INC., a Delaware corporation,	:	
	:	
	:	No.
Plaintiff,	:	
	:	
vs.	:	
	:	<b>JURY TRIAL DEMANDED</b>
THREE RIVERS PHARMACEU-	:	
TICALS, LLC, a Pennsylvania Limited	:	
Liability Company,	:	
	:	
Defendant.	:	

**COMPLAINT**

**PARTIES**

1. Plaintiff Ribapharm, Inc. (“Ribapharm”) is a corporation organized under the laws of the State of Delaware, with its principal place of business at 3300 Hyland Drive, Costa Mesa, California, 92626.

2. Defendant Three Rivers Pharmaceuticals, LLC (“3RP”) is, upon information and belief, a limited liability company organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at Cranberry Commerce Center, 312 Commerce Park Drive, Cranberry Township, Pennsylvania, 16066.

**JURISDICTION AND VENUE**

3. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 1367; and jurisdiction pursuant to 35 U.S.C. §§ 101, et seq. because this is a patent infringement action.

4. Defendant is subject to personal jurisdiction in this District because its principal place of business is located in this District, it regularly transacts business in this District, it

derives substantial revenue in this District, or has otherwise engaged in a persistent course of conduct in this District.

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

**COUNT ONE**

**PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2)(A)**

6. Plaintiff Ribapharm is the lawful owner of all right, title, and interest in and to the following United States Patents, including the right to sue and recover for infringement thereof:

a. United States Patent No. 5,767,097 (“‘097”), duly and legally issued on June 16, 1996, and entitled “SPECIFIC MODULATION OF TH1/TH2 CYTOKINE EXPRESSION BY RIBAVIRIN IN ACTIVATED T-LYMPHOCYTES.” A true and correct copy of Patent ‘097 is attached as Exhibit “A.”

b. United States Patent No. 6,063,772 (“‘772”), duly and legally issued on May 16, 2000, and entitled “SPECIFIC MODULATION OF TH1/TH2 CYTOKINE EXPRESSION BY RIBAVIRIN IN ACTIVATED T-LYMPHOCYTES.” A true and correct copy of Patent ‘772 is attached as Exhibit “B.”

c. United States Patent No. 6,150,337 (“‘337”), duly and legally issued on Nov. 21, 2000, and entitled “SPECIFIC MODULATION OF TH1/TH2 CYTOKINE EXPRESSION BY RIBAVIRIN IN ACTIVATED T-LYMPHOCYTES.” A true and correct copy of Patent ‘337 is attached as Exhibit “C.”

7. Patents ‘097, ‘772, and ‘337 were recently transferred to Plaintiff Ribapharm by their previous owner, ICN Pharmaceuticals, Inc. (“ICN”).

8. Patents ‘097, ‘772, and ‘337 are directed generally to novel uses of ribavirin.

9. Plaintiff Ribapharm markets and sells ribavirin in the United States in cooperation with its licensee, Schering Plough Corporation.

10. On April 16, 2002, ICN received from Defendant 3RP a patent certification notice ("Notice"). A true and correct copy of the Notice is attached as Exhibit "D."

11. Pursuant to the Notice and, upon information and belief, Defendant 3RP has submitted to the Federal Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA"), number 76-203, under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), to obtain approval to engage in the commercial manufacture, use, or sale of ribavirin 200 milligram capsules, a generic version of Plaintiff Ribapharm's ribavirin, before the expiration date(s) of Patents '097, '772, and '337.

12. Upon information and belief, Defendant 3RP's submission of ANDA number 76-203 constitutes an act of infringement upon one or more of Patents '097, '772, and '337 under, inter alia, the United States Patent Law at 35 U.S.C. § 271(e)(2)(A).

13. Upon information and belief, Defendant 3RP has actual or constructive knowledge, or both, of Patents '097, '772, and '337 due to widely-known information in the industry, the listing of Patents '097 and '772 in the FDA Orange Book for Rebetron™ Combination, and the Notice's acknowledgement of Patents '097 and '772.

14. Upon information and belief, Defendant 3RP's infringement of one or more of Patents '097, '772, and '337 will cause Plaintiff Ribapharm irreparable harm for which it has no adequate remedy at law, including irreparable harm within the State of California and this Judicial District, and will continue to cause such harm unless and until preliminarily and permanently enjoined by this Court.

15. Upon information and belief, Defendant 3RP's infringement of one or more of Patents '097, '772, and '337 is willful and wanton.

16. Upon information and belief, Defendant 3RP's infringement of one or more of Patents '097, '772, and '337 has or will result in substantial unjust profits for Defendant 3RP, in an amount to be determined at trial.

## **COUNT TWO**

### **PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(b)**

17. Plaintiff Ribapharm re-alleges paragraphs 1-16 inclusive.

18. Based on the Notice, Defendant 3RP knows that it will make, use, sell, or offer to sell a product, the intended use of which will infringe upon one or more of the said patents owned by Plaintiff Ribapharm in violation of the United States Patent Laws at 35 U.S.C. § 271(b).

19. Based on the Notice, Defendant 3RP has actively and knowingly aided and abetted the direct infringement of Plaintiff Ribapharm's patents, including but not limited to, providing information to medical doctors who prescribe and administer ribavirin in a manner which infringes upon one or more of Plaintiff Ribapharm's said patents.

20. Based on the Notice, Defendant 3RP's acts of infringement were done with the specific intent to cause the direct infringement by others, including but not limited to, medical doctors who prescribe and administer ribavirin in a manner which infringes upon one or more of Plaintiff Ribapharm's said patents.

21. Upon information and belief, Defendant 3RP has actively induced others, including but not limited to, medical doctors who prescribe and administer ribavirin, to infringe

upon one or more of Plaintiff Ribapharm's said patents, in violation of the United States Patent Law at 35 U.S.C. § 271(b).

**COUNT THREE**

**INTENTIONAL INTERFERENCE WITH PROSPECTIVE CONTRACTUAL RELATIONS**

22. Ribapharm re-alleges paragraph 1-21 inclusive.

23. Upon information and belief, Defendant 3RP's acts of patent infringement upon FDA approval of 3RP's ANDA and 3RP's preparation for commercial development of the subject matter, claims, or inventions in Patents '097, '772, and '337, have been, and continue to be, improperly and intentionally interfering with Ribapharm's prospective contractual relations with others.

24. 3RP's acts of patent infringement, including inducing infringement, have resulted in, and are currently resulting in, substantial loss of prospective business revenue and good will in an amount to be determined at trial.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Ribapharm asks this Court to:

- A. Enter judgment for Plaintiff on this Complaint.
- B. Enter a preliminary and permanent injunction against Defendant 3RP, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Federal Rule of Civil Procedure 65 that:
  - i. Prevents Defendant 3RP and those in privity with or acting in concert with Defendant 3RP, its subsidiaries, officers, directors, agents, servants, employees, and all persons acting for, with, by, through or under them, or any individual in active concert or in participation with them, from commercially manufacturing, using, offering to sell, or selling within the United

States, or importing into the United States any drug product or precursor that infringes upon Patents '097, '772, and '337 during the remainder of the terms for which they have been granted.

ii. Requires Defendant 3RP to prepare and deliver to the Court a complete list of persons and entities whom Defendant 3RP has contacted for the purpose of infringing, inducing, or contributing to the infringement of one or more of Patents '097, '772, and '337, and to serve a copy of such list on Plaintiff Ribapharm's attorneys.

iii. Requires Defendant 3RP to inform all persons and entities on the said list about: (1) the existence of Patents '097, '772, and '337; (2) the methods encompassed by those Patents; and (3) the illegality of infringing any of those Patents.

iv. Requires Defendant 3RP to deliver to the Court any and all documents reflecting or relating to the infringement of one or more of Patents '097, '772, and '337, with copies thereof to be delivered to counsel for Plaintiff Ribapharm.

v. Requires Defendant 3RP to deliver up to the Court its inventory of all products which infringe upon one or more of Patents '097, '772, and '337, with a list of all infringing products to be delivered to counsel for Plaintiff Ribapharm.

vi. Requires Defendant 3RP within thirty (30) days after entry of judgment to file with the Court, and serve on Plaintiff Ribapharm's attorneys, a written report, under oath, setting forth in detail the manner in which Defendant 3RP has complied with paragraphs i through v above.

C. Award Plaintiff Ribapharm damages against Defendant 3RP adequate to compensate Plaintiff Ribapharm for Defendant 3RP's acts of infringement, inducement of, or contribution to infringement, together with interest and costs, and to increase the damages by three times the amount found, in accordance with 35 U.S.C. § 284.

D. Find the present case exceptional and therefore award attorneys' fees to Plaintiff Ribapharm under 35 U.S.C. §§ 271(e)(4) and 285.

E. Order the FDA not to approve the ANDA No. 76203 submitted by Defendant 3RP as long as said patents are in force.

F. Provide Plaintiff Ribapharm such other and further relief as the Court may deem appropriate.

**JURY DEMAND**

Plaintiff Ribapharm hereby demands trial by jury on all issues triable to a jury.

Dated: May 24, 2002

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